

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

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K962393

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Device Identification: **Common Name:**
Telescopes and accessories used in Laryngoscopy

Trade Name: (optional)
Karl Storz Set for Endoscopic Assisted Intubation

Indication: The KSEA Set for Endoscopic Assisted Intubation is designed to be used by qualified surgeons and physicians to view the larynx during intubation.

Device Description: The KSEA Set for Endoscopic Assisted Intubation is comprised of a Rigid Telescope and a BUMM Clip. KSEA Rigid Telescopes for Endoscopic Assisted Intubation are rigid, straight-shafted, panoramic telescopes which utilize Hopkins rod-lens technology. The KSEA BUMM Clip is used to secure the KSEA rigid telescope to a laryngoscope. The body contact portions of the KSEA Set for Endoscopic Assisted Intubation are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

Substantial Equivalence: The KSEA Set for Endoscopic Assisted Intubation is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA Set for Endoscopic Assisted Intubation and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Signed:


Kevin Kennan
Regulatory Affairs Specialist